

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **See form PCT/ISA/210**

Applicant's or agent's file reference

S 2892

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/EP2005/002057

International filing date (day/month/year)

26.02.2005

Priority date (day/month/year)

28.02.2004

International Patent Classification (IPC) or both national classification and IPC

C12P19/22, C12P19/14, C08B30/20, A61K31/718, C08B35/00, A61K47/48

Applicant

SUPRAMOL PARENTERAL COLLOIDS GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. II

Priority

1. ☐ The following document has not yet been furnished:
- ☐ copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).
- Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date in the claimed priority date.
2. ☒ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
- The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.

**WRITTEN OPINION OF THE
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International application No.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-8</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims _____	YES
	Claims <u>1-8</u>	NO
Industrial applicability (IA)	Claims <u>1-8</u>	YES
	Claims _____	NO

2. Citations and explanations:

1. Documents

1.1 This opinion cites the following search report citations (D);
the same numbering will be used throughout the procedure:

1.2 **D1:** US5886168
D2: US20040014961
D3: GB2342656

2. Novelty (PCT Article 33(3))

2.1 The present application meets the requirements of PCT Article 32(2) because **the subject matter of claims 1-8 is novel** under PCT Rule 64(1) to (3).

3. Inventive step (PCT Article 33(3))

3.1 The present application does not meet the requirements of PCT Article 33(3) because **the subject matter of claims 1-8 is not inventive** under PCT Rule 65(1) to (2).

3.2 Claim 1 of the application describes a process for preparing hyperbranched amylopectin having a molecular weight of ≥ 2000 daltons and $\leq 30\ 000$ daltons and a degree of branching of $\geq 10\%$ and $\leq 20\%$. The process consists of two hydrolysis steps:

1) by means of α -amylase or acid hydrolysis, the molecular weight of the amylopectin is degraded to $\leq 60\ 000$ daltons,

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2) by means of β -amylase, the molecular weight of the degradation product from the first step is degraded further, to the desired 2000-30 000 daltons.

3.3 Document **D1**, which is considered to be the closest prior art, discloses (abstract, claim 1, examples) a process for preparing branched amylopectin having a molecular weight of 20 000-50 000 daltons utilizing α -amylase.

3.4 The process of claim 1 of the application differs from **D1** in that a second β -amylase step is performed in order to bring the amylopectins to a molecular weight of 2000-30 000 daltons and a degree of branching of 10-20%.

3.5 However, this difference cannot be considered to be inventive.

3.6 **D2** (paragraphs 121, 122) discloses a process for preparing branched amylopectin having a degree of branching of 10-30% by performing a second hydrolysis step with, for example, β -amylase in order to increase the degree of branching and to degrade the molecular weight.

3.7 A person skilled in the art with knowledge of **D1** and with the problem of preparing an amylopectin with molecular weight of 2000-30 000 and a degree of branching of 10-20% would utilize the disclosure of **D2** in order to achieve the further degradation and the desired degree of branching of the amylopectin of the **D1** process. A person skilled in the art would, without thereby needing to be inventive, arrive at the optimal reaction conditions.

3.8 It also becomes clear from **D3** (abstract) that α -amylase and acid hydrolysis can be considered as alternative processes to arrive at a degraded amylopectin.

3.9 Claim 1 therefore cannot be considered to be inventive.

3.10 Dependent claims 2-8 do not contain any features which, in

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combination with the features of any claim to which they refer, meet the PCT requirements for inventive step. Claims 2-8 are therefore considered not to be inventive over the cited prior art and/or the common general knowledge of a person skilled in the art.

4. Further remarks

- 4.1 At page 4 line 17 the molecular weight is reported as $\leq 29\ 000$. However, claim 1 reports the molecular weight as $\leq 30\ 000$.
- 4.2 The cited document DE10254754.9 (page 7 line 13) cannot be found.
- 4.3 Pursuant to PCT Rule 5.1(a)(ii), the description should have cited documents **D1-D3** and briefly outlined the relevant prior art contained therein.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO2004050710	17.06.2004	03.12.2003	04.12.2002

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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See form 210